



EXECUTION VIEWER

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FUNCTIONAL REQUIREMENT SPECIFICATION

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1 Introduction

This document details the requirements of the functions implemented related to viewing execution processes with PharmaSuite Production Execution Viewer.

Each requirement is composed of a name (e.g., Access Control) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

In some cases, additional context information is available, indicated in the document by a frame and a gray background color. This context information is related to the respective requirement, but not part of the formal requirement description.

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as <ul style="list-style-type: none">▪ window and dialog titles▪ menu functions▪ panel, tab, and button names▪ box labels▪ object properties and their values (e.g., status).
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2 Production Execution Viewer (SR3300+)

In PharmaSuite, an operator is guided by the Production Execution Client with a focus on the next task that needs to be completed at the current station.

Production Execution Viewer provides a complete overview of an order or workflow that is currently in process or has already been processed. Thus, it can support various roles in various scenarios:

- an operator who works on several stations simultaneously to determine on which station an upcoming task needs to be completed next.
- during shift change to ensure a smooth hand-over by providing the new shift with an overview of the current order.
- a support person to access processed data of previous operations or unit procedures in order to understand and quickly resolve issues during production.

2.1 GID-2665877 Access Control (SR3300.1)

The access control of Production Execution Viewer enables the definition of user-specific access rights.

The system allows only authorized users to launch Production Execution Viewer.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

2.2 GUI Components (SR3300.2+)

The system provides different windows as part of Production Execution Viewer. It allows to display orders and workflows to view their data in various panels.

2.3 GID-2665879 Menu Bar (SR3300.2.1)

The menu bar offers a **File** menu with following functions:

- Open
- Refresh from Database
- Close
- Close all
- Print report
- Exit

The menu bar offers a **Find** menu with following functions:

- Find
- Find again

The menu bar offers a **View** menu with following functions:

- Zoom (Zoom to fit, Zoom to 100%, Zoom in, Zoom out)
- Show/hide grid
- Show/hide Map
- Show/hide Explorer
- Show/hide Element properties
- Show/hide Source properties
- Show/hide Header properties
- Show/hide Phase view

The menu bar offers a **Window** menu with following functions:

- Undo layout change
- Redo layout change
- Save user layout
- Load user layout
- Reset layout

The menu bar offers a **Help** menu with following functions:

- Production Execution Viewer Help
- About FT PharmaSuite

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.4 GID-2665880 Toolbar (SR3300.2.2)

The following action buttons are available from the **File** toolbar:

- Open: It opens the Open dialog of the production execution viewer to select an order or workflow for opening it in the Graph Window.
- Refresh: It reloads the data of the graph in the currently active tab from the database.
- Close: It closes the main component tab that is currently active in the upper tab bar. This action also closes all of its subordinate components tabs that may be open in the lower tab bar.

The following action buttons are available from the **View** toolbar:

- Zoom to 100%; It resets the zoom factor of the currently active graph to its default value.
- Zoom in: It zooms in on the graph in the currently active tab, doubling its display size.
- Zoom out: It zooms out from the graph in the currently active tab, reducing its size to half of its previous display size.

The following action buttons are available from the **Help** toolbar:

- Help: It opens a web browser to display the context-sensitive help of Production Execution Viewer.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.5 GID-2665881 Map (SR3300.2.3)

The Map displays the current element and its superordinate elements in three views and enables the navigation through the order or workflow. The view of the current Graph Window is highlighted. The Map applies to order/workflow level, unit procedure level, and operation level.

The view of an element differs depending on its processing status:

- Processing never started.
- Processing started but has not finished yet and no superordinate element has finished processing.
- Processing was started and has finished, or a superordinate element has finished processing.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.6 GID-2665882 Explorer (SR3300.2.4)

The Explorer displays a structural overview of the graph and enables the navigation through the order or workflow.

A corresponding marker indicates a graph element's processing status:

- Processing started but has not finished yet and no superordinate element has finished processing.
- Processing was started and has finished, or a superordinate element has finished processing.

A number in front of a graph element is displayed if more than one run is available (e.g., a unit procedure is reactivated, several ETOs of the same template are triggered or a phase is looped). Since several runs are represented by one graph element in the explorer, only the identified run [including its run number] and the processing status of the last run can be displayed.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.7 GID-2665883 Workflows Appended to Order Steps (SR3300.2.4.1)

In case the explorer represents the structural overview of an order graph, and a unit procedure of the order has one or more workflows appended, the appended workflow is available and can be accessed from the explorer.

The unit procedure explorer node displays the workflows after the operations of the unit procedure. A workflow -specific icon is used to visually differentiate between an appended workflow and an operation of the unit procedure.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.8 GID-2665884 Graph Window (SR3300.2.5)

The Graph Window can display more than one order or workflow, each in a separate, upper tab with the respective order or workflow identifiers as tab titles.

Order and workflow data is read-only.

- All upper tabs can be closed separately.
- All tabs can be closed, one at a time, except for the current order or workflow.
- The Graph Window can display more than one graph element of an order or workflow in separate lower tabs of an upper tab.
- Lower tabs can be closed separately.
- All lower tabs can be closed one at a time except for the current tab.
- The tab titles of lower tabs display the respective graph element identifiers.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.1 GID-2665885 Graph Element (SR3300.2.5.1)

A graph element can represent a procedure, a unit procedure, an operation, or a phase. The images of graph window elements change their representations depending on their current processing status:

- Processing never started.
- Processing started but has not finished yet and no superordinate element has finished processing.
- Processing was started and has finished, or a superordinate element has finished processing.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.1.1 GID-2667111 ELEMENT WITH EXCEPTIONS (SR3300.2.5.1.1)

The element displays the number of exceptions including exceptions of subordinate elements and shows a red marker in its left upper left corner if at least one exception has been registered for it.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.9 GID-2665886 Property Windows (SR3300.2.6)

The property window displays data of the element that is currently selected in the active tab of the Graph Window. All data is read-only.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.1 GID-2665887 Property Window - Header (SR3300.2.6.1)

Provides the properties of the header component (order and its master recipe or workflow and its master workflow):

- Identifier (of order or workflow)
- Type (Batch or Workflow)
- Status (of order or workflow)
- Master recipe or master workflow
- Description (of master recipe or master workflow)
- Master recipe or master workflow status

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.2 GID-2665888 Property Window - Element (SR3300.2.6.2)

Provides the properties of the selected element in the currently active tab of the graph window.

- In case the processing of the element is not started, its identifier and description.
- In case the processing of the element was already started the data depends on the level.
- For a phase:
Identifier [including run number], Created at, Start time, Completion time, Work center, Station, Device, Phase name, Description.
- For an operation:
Identifier [including run number], Status, Created at, Completion time, Station, Operation name, Description.
- For a unit procedure:
Identifier [including run number], Status, Created at, Completion time, Work center, Unit procedure name, Description.

Even after a detach action and starting the operation afterwards at a different work center or station, the initially used work center and station are displayed.
Phases started for the first time after detaching will display the new work center and station name.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.3 GID-2665889 Property Window - Source (SR3300.2.6.3)

Provides the properties of the source system/custom building block that was used as a template to create the master recipe or master workflow.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.4 GID-2665890 Phase View (SR3300.2.7)

The phase view panel consists of the phase view of the element selected in the currently active tab of the graph window and displays how the selected phase was rendered during execution. The preview of a phase is shown as long as the phase has not been started or has been started but has not been confirmed yet by the operator. The completed view of a phase is displayed as soon as the phase execution has been confirmed by the operator. A phase for which an exception has been recorded displays an exception marker on its completed view.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.9.5 GID-2665891 Docking (SR3300.2.8)

The docking configuration is available as a default layout and a user-specific layout.

In the default docking configuration, the windows are arranged as follows:

- To the left of the Graph Window: **Explorer (SR3300.2.4)** tool (GID-2427139).
- To the left of the Explorer Window: **Map (SR3300.2.3)** tool link
- At the bottom of the Graph Window: **Phase View (SR3300.2.7)** GUI component (GID-2427148)
- To the left of the Phase View Window: Property Windows ((GID-2427144)) GUI component link.

The following functions are available to maintain the docking configuration:

- Undo last layout changes related to the dockable windows.
- Redo last layout changes related to the dockable windows.
- Save the window layout (user-specific).
- Load the last saved window layout (user-specific).
- Reset the window layout to the default layout.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10 Viewer Management (SR3300.3+)

2.10.1 GID-2665893 Open Dialog (SR3300.3.1)

The open dialog opens the selected order or workflow. It allows to select data records for opening in a resizable dialog. It provides an intelligent filter and search function.

Only orders or workflows are available that are currently in process or have already been processed.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.1.1 GID-2667112 OPEN DIALOG QUICK SEARCH (SR3300.3.1.1)

A quick search function applies to the search result and reduces the result according to the filter criteria.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.1.2 GID-2667113 OPEN DIALOG FILTER (SR3300.3.1.2)

The filter provides the following selection criteria to reduce the subsequent search results:

- Object type
- Status (of order or workflow)
- Material (only for order)
- Batch (only for order)
- Type (only for workflow)

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.1.3 GID-2667114 OPEN DIALOG SEARCH RESULT (SR3300.3.1.3)

The search result is available in a separate table. The result data records contain the following information:

- Identifier
- Status (of order or workflow)
- Material identifier (only for order)

- Short description (of material, only for order)
- Quantity (only for order)
- Type (only for workflow)
- Processing name (only for workflow)
- Detail (only for workflow)

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.1.4 GID-2667115 OPEN DIALOG FOR PROTECTED OBJECTS (SR3300.3.1.4)

For orders and workflows that are protected by an access privilege due to its related master recipe or master workflow, respectively: The system shall only provide orders and workflows for selection whose access privilege matches the access privilege of the logged-in user.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.2 Graph Element Actions (SR3300.3.2+)

Several actions are available for a selected element in the currently active tab of the graph window.

2.10.2.1 GID-2667116 EXCEPTION LIST (SR3300.3.2.1)

Exceptions of the element with their comments can be displayed in a grid. This includes exceptions of subordinate elements.

The data set of an exception/comment consists of the following data:

- (Book)mark
- Identifier
- Exception text / comment
- Status
- Category
- Risk
- Classification (configurable)
- Result
- CAPA ID (configurable)
- Communication status (configurable)

- External ID (configurable)
- Reference (path)
- Signatures

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.2.2 GID-2667117 EXCEPTION QUICK SEARCH (SR3300.3.2.1.1)

The system provides a search possibility on the displayed exception and comment data.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.2.3 GID-2667118 PREVIEW AND PRINT A REPORT (SR3300.3.2.2)

A report of an element including all its subordinate elements can be opened for previewing and with the possibility to print it.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.2.4 GID-2667119 RUN LIST (SR3300.3.2.3)

All runs of a graph element can be displayed in a grid. The list is sorted by the identifier of the run (including the path up to the unit procedure).

A double click on a run opens it as a new footer tab next to the current graph and closes the grid.

A right mouse click on a run opens a context menu. A context menu action allows to open the run as a new footer tab next to the current graph in the background and keeps the grid open.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.10.2.5 GID-2667120 OUTPUT VARIABLE DATA (SR3300.3.2.4)

For all completed phases, it is possible to view a list of their phase-specific output variables by clicking the **Phase Output** icon. Output variable data will be presented as name and value pairing. Output variable data of the framework (Instance count, Start time, Completion time, Identifier) is only displayed in the property window.

- Output variable values of the decimal and DateTime data type will be client-localized.
- Output variable data will be alphabetically ordered.
- In case an output variable data value is not set, it will be presented as empty field.
- The value of an output variable of the IMESS88Equipment data type will contain the identifier of the equipment.
- The name of a bundle output variable is a concatenation of the bundle identifier and the output variable name.
- A data reference output variable of the PhaseDataReference data type is not displayed.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

3 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

4 Document Information

The document information covers various data related to the document.


4.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Wolfgang Schmitt	Technical Lead
Ignaz Wangler	Test Lead

4.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Functional Requirement Specification	1.0



5 Appendix A - Revision History

5.1 Updated Requirements

None

5.2 Added Requirements

None

5.3 Deleted Requirements

None



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